



11-01-04

AF/3743
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: David Scott Gray
Serial No.: 09/934,016
Filed: 08/20/2001
For: Medical Port for an Emergency Safety Resuscitator
Confirmation No.: 7568
Group Art Unit: 3743
Examiner: Mital B. Patel
Customer No.: 31198
Attorney Docket No.: PGRACT

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Date of Deposit: October 29, 2004

I hereby certify that the following attached

Appellant's Brief

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Mail Stop Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Thompson E. Fehr
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APPELLANT'S BRIEF (37 CFR 41.37)

This brief is in furtherance of the Notice of Appeal filed in this case on April 29, 2004.

The fees required under § 41.20 and any required petition for extension of time for filing this brief and fees therefor are dealt with in the accompanying TRANSMITTAL OF APPEAL BRIEF.

11/03/2004 AWONDAF1 00000028 09934016

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11/03/2004 AWONDAF1 00000070 09934016

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This brief contains the following items, under headings of the same name and in the order given:

REAL PARTY IN INTEREST
RELATED APPEALS AND INTERFERENCES
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STATUS OF AMENDMENTS
SUMMARY OF CLAIMED SUBJECT MATTER
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CLAIMS APPENDIX

The final page of this brief bears the attorney's signature.

REAL PARTY IN INTEREST

The real party in interest is David Scott Gray.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellants or Appellants' legal representative which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS

Claims 1 and 2 have been canceled.

Claim 3 has been rejected.

Claim 4 has been objected to and rejected.

Claims 5 and 6 have been rejected.

Claim 7 has been canceled.

Claims 8, 9, 10, and 11 have been rejected.

Claim 12 has been canceled.

The claims being appealed are claims 3 through 6 and 8 through 11.

STATUS OF AMENDMENTS

An amendment was filed on October 28, 2004, correcting a grammatical error in claim 4 to overcome the objection and place it in better form for appeal. Appellant believes this is permitted by 37 CFR 41.33(a) but is somewhat confused since 37 CFR 1.116 does not seem to refer to the date a brief is filed. At the time this appeal was filed, the present restrictions on filing amendments, furthermore, did not exist.

SUMMARY OF CLAIMED SUBJECT MATTER

As indicated in lines 2 through 5 on page 2, 3 through 6 on page 3, and 1 through 8 as well as 17 through 20 on page 4 of the present application, United States patent nos. 6,062,217 and 6,276,363 (of which the present application is a continuation-in-part) cover a prior invention:

The prior invention inserts, between a source of air or oxygen and a patient a collapsible bag and a connecting complex. A nebulizer or aerosolizer for providing medication can be attached to the connecting complex. Additionally, the connecting complex includes an aperture with a removably attached self-sealing membrane through [which] medications can be administered with a syringe. When the self-sealing membrane has been removed, a suction catheter may be placed through the aperture.

The connecting complex can communicate with the patient either through a mask or an endotracheal tube.

As indicated with more detail in lines 10 through 16 on page 7 and line 26 of page 7 through line 7 of page 8 as well as in Figures 1, 2, and 5 of the application:

Attached to and communicating with a second end **20** of the housing **18** is a first aperture **23** of a tube **24**. The tube **24** is preferably L-shaped. And the hollow three-armed connector **7**, the housing **18**, and the tube **24** are preferably constructed of rigid clear plastic.

A second aperture **25** of the tube **24** is releasably covered by a self-sealing membrane **26**. The self-sealing membrane is preferably siliconized.

To a third aperture **27** of the tube **24** may be connected either a mask or an endotracheal tube.

...

Preferably, first ends **28** of strips of flexible plastic **29** are attached to the inside **30** of the tube **24** between the first aperture **23** and the second aperture **25**. The second ends **31** of the strips of flexible plastic **29** push against one another so that when a suction catheter is inserted, a seal is formed between the inside **30** of the tube **24** and the suction catheter to preclude contamination from the patient escaping into the atmosphere. The location of the strips of flexible plastic **29** prevents their interfering with the flow of oxygen from the first aperture **23** to the third aperture **27**.

The present invention, furthermore, makes the tube 24 available as a separate unit to attach directly to and communicate with the collapsible bag 1 of any resuscitator. A hollow adapter 37 has a first end 38 that attaches to and communicates with the outlet 39 of the collapsible bag 1 and a second end 40 which attaches to the tube 24 around the first aperture 23. Preferably, the hollow adapter 37 is constructed of rigid clear plastic.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The Examiner has rejected claims 3 and 10 under 35 U.S.C. § 102(b) as being anticipated by Coles et al. (United States patent no. 5,513,628).

Claims 4 and 11 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Coles et al. (United States patent no. 5,513,628) in view of Wilson (United States patent no. 4,106,502).

Claims 6 and 9 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Coles et al. (United States patent no. 5,513,628) in view of Rosenblatt (United States patent no. 4,950,247).

Claim 5 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Coles et al. (United States patent no. 5,513,628) and Wilson (United States patent no. 4,106,502) as applied to claim 4 and further in view of Rosenblatt (United States patent no. 4,950,247).

And claim 8 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Coles et al. (United States patent no. 5,513,628) in view of Wilson (United States patent no. 4,106,502) and further in view of Rosenblatt (United States patent no. 4,950,247).

ARGUMENT

Claim 3

35 U.S.C. § 102

The Examiner, in his Office Action mailed on October 29, 2003, has declared:

As to claim 3, Coles teaches a medical port **105** for an emergency safety resuscitator having a collapsible bag with an outlet which comprises a tube having a first aperture **135** for communicating with a collapsible bag of a resuscitator, a second aperture **120**, a third aperture **140** available for connection to a mask or an endotracheal tube, and an inside; a self-sealing membrane **145** releasably covering the second aperture of the tube; and two or more strips of flexible plastic **155**, each strip having a first end attached to the inside of the tube, between the first aperture and the second aperture, and a second end pushing against a second end of at least one other of the strips (See Fig. 1).

Appellant respectfully suggests that element **145** in Coles (United States patent no. 5,513,628) is not a self-sealing membrane.

This element appears to be discussed in three locations in Coles.

Lines 66 in column 6 through 4 in column 7 provide:

A dust cap, typically tethered to the manifold, may be placed over the proximal end of the manifold between suction procedures. The dust cap acts as a protective sterile barrier between the suction procedures as well as a seal against pressure differentials across the manifold to prevent back flow through the normally closed directional barrier.

Line 61 in column 7 through line 9 in column 8 declare:

A cap **145**, capable of covering the proximal end **120** of the body **110**, may be attached to the body **110** with a tether **150**. Situated within the space **125** of the body **110** is a directional barrier **155** preferably formed of a pliant, durable, rubber-like material with strong dimensional memory. The directional barrier **155** includes a central aperture **157**. The directional barrier **155** is seated around its entire cross-sectional periphery against a rim **160** extending inwardly from the internal wall of the body **110**. The barrier **155** and the rim **160** interface in a manner that achieves a sealing and anchoring of the directional barrier **155** relative to the body **110**. A seal extension **165** may protrude slightly from the directional barrier **155** axially beyond the proximal end **120** of the body **110** to

provide additional sealing effect between the cap 145 and the body 110 when the cap 145 is in position to cover the proximal end 120 of the body 110.

And lines 24 through 30 in column 9 state:

The practitioner may then, with minimal waste and cost, discard the catheter 220 and adapter structure 185 and place the cap 145 over the proximal end 120 of the manifold assembly 105 until next use, leaving no partially obstructed catheter, plastic envelope and complicated valve structure to interfere with other procedures and auxiliary equipment.

Appellant respectfully observes that nowhere within the patent application of Coles can Appellant find any indication that the cap 145 is a “self-sealing membrane.”

Furthermore, Appellant respectfully believes that element 155 of Coles is not “two or more strips of flexible plastic.”

Lines 6 through 27 in column 4 of the Coles patent explain:

. . . A directional barrier is carried by the proximal end portion of the manifold assembly. It is constructed and arranged to effect a seal against fluid flow through the open interior of the manifold towards the proximal end portion but to pass a catheter introduced through the proximal end portion.

Preferably, the directional barrier is configured to be inserted in the proximal end portion in sealing relationship with the open interior, and comprises a normally closed valving structure. The normally closed valve structure may be constructed and arranged to effect a sliding seal arrangement with the external surface of a catheter passed through the body of the manifold; that is, from the proximal end portion towards the distal end portion through the valve structure. Preferably, the valve and catheter carrier are mutually adapted to effect this sliding seal. The valve structure may carry detection means constructed and arranged to signal the precise location of the tip of a catheter positioned within the valve structure. For example, these means may signal, by resistance to travel or sound, the presence of the tip when it is moved to the proximity of the valve structure from a location closer to the distal end portion of the manifold assembly.

Lines 40 through 60 in column 4 of the Coles patent continue:

. . . The introducer structure is constructed and arranged to interface with the directional barrier when the leading end portion of the carrier is coupled with the proximal end portion of the manifold. For example, it may comprise an introducer tip constructed as a continuous wall to define an interior passageway

configured to receive and pass a catheter and an exterior surface configured to interface with the directional barrier. The directional barrier is further preferably structured to effect a resilient seal against an internal surface of the continuous wall. The interior passageway may include an entry constructed and arranged to effect a sliding seal with the exterior surface of a catheter. In any event, the exterior surface of the introducer tip and the directional barrier are mutually adapted to effect a sealed relationship when the leading end portion of the catheter carrier is coupled with the proximal end portion of the manifold body.

The directional barrier may be structured to effect a resilient seal both against an internal surface of the open interior of the manifold body and between the proximal end portion of the body and the catheter carrier.

Most significantly, lines 26 through 35 in column 5 of the Coles patent describe the structure of the directional barrier 155:

The directional barrier may be configured as an elongate pressure and sterility barrier, and the normally closed valve may be in the shape of a duckbill, with a normally closed central aperture interposed within the passageway of the manifold. Whether the barrier is structured to include an aperture of elongate transverse dimension or a simple slit in a membranous end of the barrier wall, the barrier in combination with the adapter assembly provides an effective seal against patient expectoration, contaminant migration and pressure leakage.

Consistently, line 63 in column 7 through line 9 in column 8 declare:

... Situated within the space 125 of the body 110 is a directional barrier 155 preferably formed of a pliant, durable, rubber-like material with strong dimensional memory. The directional barrier 155 includes a central aperture 157. The directional barrier 155 is seated around its entire cross-sectional periphery against a rim 160 extending inwardly from the internal wall of the body 110. The barrier 155 and the rim 160 interface in a manner that achieves a sealing and anchoring of the directional barrier 155 relative to the body 110. A seal extension 165 may protrude slightly from the directional barrier 155 axially beyond the proximal end 120 of the body 110 to provide additional sealing effect between the cap 145 and the body 110 when the cap 145 is in position to cover the proximal end 120 of the body 110.

Appellant certainly understands that Fig. 1 in Coles, being a cross-sectional view, is misleading. The textual discussion in Coles, however, clarifies that the directional barrier 155 is a structure having a rim 160 and a central aperture 157. The aperture "may be in the shape of a

duckbill, with a normally closed central aperture interposed within the passageway of the manifold." Fig. 1 is apparently the embodiment utilizing the duckbill shape with an aperture. In a cross-sectional view, the duckbill falsely appears to be two strips.

Even, however, were there two strips, the first end of each strip would be attached to the rim **160**, not to the tube.

For the preceding reasons, Appellant respectfully asserts claim 3 is patentable and that Coles does not anticipate claim 3.

Claim 4

35 U.S.C. § 103

The Examiner has further, in his Office Action mailed on October 29, 2003, stated:

As to claims 4 and 11, Coles teaches essentially all of the limitations except for wherein the tube is constructed of clear plastic. However, Wilson does teach the use of a clear plastic for the construction of tube so that the tube is lightweight and allows for internal viewing or visibility. Therefore, it would have been obvious to one of ordinary skill in the art to modify the tube of Coles and construct the tube of a clear plastic so that the tube is lightweight and allows for internal viewing or visibility.

In view of the discussion above concerning Coles, Appellant respectfully believes that combining Wilson with Coles would not create the device of claim 4 and, therefore, that claim 4 is not unpatentable over Coles et al. in view of Wilson.

Claims 5 and 6

35 U.S.C. § 103

The Examiner has also, in his Office Action mailed on October 29, 2003, asserted:

As to claim 5, the combination of Coles and Wilson teaches essentially all of the limitations except for wherein the self-sealing membrane is siliconized. However, Rosenblatt does teach the use of a silicon since it is a material that has

memory so that any element formed from silicon would return to its original shape if that element is deformed without requiring the use of a spring or other elastic material to bring the element back to shape. Therefore, it would have been obvious to one of ordinary skill in the art to make the self-sealing member of Coles from silicon so that it can return to its original shape after being deformed.

and

As to claim 6, Coles teaches essentially all of the limitations except for wherein the seal-sealing member is siliconized. However, Rosenblatt does teach the use of a silicon since it is a material that has memory so that any element formed from silicon would return to its original shape if that element is deformed without requiring the use of a spring or other elastic material to bring the element back to shape. Therefore, it would have been obvious to one of ordinary skill in the art to make the self-sealing member of Coles from silicon so that it can return to its original shape after being deformed.

Rosenblatt (United States patent no. 4,950,247) utilizes silicon rubber in a bellows for the purpose stated by the Examiner. Appellant, however, respectfully suggests that acting like a spring is the function of a bellows but is a completely different function from having a material which has been punctured with a needle seal itself.

For this reason and also in view of the discussion concerning Coles above, Appellant respectfully asserts the claims 5 and 6 are patentable and not obvious over Coles et al. and Wilson as applied to claim 4 and further in view of Rosenblatt or over Coles et al. in view of Rosenblatt.

Claims 8 and 9

With respect to claims 8 and 9, the Examiner has written, in his Office Action mailed on October 29, 2003:

As to claim 8, Coles teaches a medical port **105** for an emergency safety resuscitator having a collapsible bag with an outlet which comprises a tube having a first aperture **135** for communicating with a collapsible bag of a resuscitator, a second aperture **120**, a third aperture **140** available for connection to a mask or an endotracheal tube, and an inside; and a self-sealing membrane **145** releasably

covering the second aperture of the tube. Coles teaches essentially all of the limitations except for wherein the tube is constructed of clear plastic. However, Wilson does teach the use of a clear plastic for the construction of tube so that the tube is lightweight and allows for internal viewing or visibility. Therefore, it would have been obvious to one of ordinary skill in the art to modify the tube of Coles and construct the tube of a clear plastic so that the tube is lightweight and allows for internal viewing or visibility. The combination of Coles and Wilson teaches essentially all of the limitations except for wherein the self-sealing membrane is siliconized. However, Rosenblatt does teach the use of a silicon since it is a material that has memory so that any element formed from silicon would return to its original shape if that element is deformed without requiring the use of a spring or other elastic material to bring the element back to shape. Therefore, it would have been obvious to one of ordinary skill in the art to make the self-sealing member of Coles from silicon so that it can return to its original shape after being deformed.

...

As to claim 9, Coles teaches a medical port **105** for an emergency safety resuscitator having a collapsible bag with an outlet which comprises a tube having a first aperture **135** for communicating with a collapsible bag of a resuscitator, a second aperture **120**, a third aperture **140** available for connection to a mask or an endotracheal tube, and an inside; and a self-sealing membrane **145** releasably covering the second aperture of the tube. Coles fails to specifically teach the seal-sealing member to be siliconized. However, Rosenblatt does teach the use of a silicon since it is a material that has memory so that any element formed from silicon would return to its original shape if that element is deformed without requiring the use of a spring or other elastic material to bring the element back to shape. Therefore, it would have been obvious to one of ordinary skill in the art to make the self-sealing member of Coles from silicon so that it can return to its original shape after being deformed.

For the same reasons as explained with respect to claims 5 and 6 (except those dealing with Coles et al. and strips of flexible plastic since they are not present in claims 8 and 9), Appellant respectfully submits that claims 8 and 9 are patentable and not unpatentable over Coles et al. in view of Rosenblatt or over Coles et al. in view of Wilson and further in view of Rosenblatt.

Claim 10

35 U.S.C. § 102

Concerning the rejection of claim 10, the Examiner has, in his Office Action mailed on October 29, 2003, observed:

As to claim 10, Coles teaches a medical port **105** for an emergency safety resuscitator having a collapsible bag with an outlet which comprises a tube having a first aperture **135** for communicating with a collapsible bag of a resuscitator, a second aperture **120**, a third aperture **140** available for connection to a mask or an endotracheal tube, and an inside; and two or more strips of flexible plastic **155**, each strip having a first end attached to the inside of the tube, between the first aperture and the second aperture, and a second end pushing against a second end of at least one other of the strips.

For the reasons discussed earlier with respect to the plastic strips in association with the rejection of claim 3, Appellant respectfully submits that claim 10 is patentable because Coles does not anticipate claim 10.

Claim 11

35 U.S.C. § 103

Finally, as noted above, the Examiner has, in his Office Action mailed on October 29, 2003, provided:

As to claims 4 and 11, Coles teaches essentially all of the limitations except for wherein the tube is constructed of clear plastic. However, Wilson does teach the use of a clear plastic for the construction of tube so that the tube is lightweight and allows for internal viewing or visibility. Therefore, it would have been obvious to one of ordinary skill in the art to modify the tube of Coles and construct the tube of a clear plastic so that the tube is lightweight and allows for internal viewing or visibility.

For the same reasons as given concerning claim 10, Appellant respectfully suggests that claim 11 is patentable and not unpatentable over Coles et al. in view of Wilson.

Appellant respectfully requests that the Board reverse the decision of the Examiner and rule that claims 3 through 6 and 8 through 11 are allowable.

CLAIMS APPENDIX

Claim 3. A medical port for an emergency safety resuscitator having a collapsible bag with an outlet, which comprises:

a tube having a first aperture for communicating with a collapsible bag of a resuscitator, a second aperture, a third aperture available for connection to a mask or an endotracheal tube, and an inside;

a self-sealing membrane releasably covering the second aperture of said tube; and two or more strips of flexible plastic, each strip having a first end attached to the inside of said tube, between the first aperture and the second aperture, and a second end pushing against a second end of at least one other of said strips.

Claim 4. The medical port for an emergency safety resuscitator having a collapsible bag with an outlet as recited in claim 3, wherein:

said tube are constructed of rigid clear plastic.

Claim 5. The medical port for an emergency safety resuscitator having a collapsible bag with an outlet as recited in claim 4, wherein:

said self-sealing membrane is siliconized.

Claim 6. The medical port for an emergency safety resuscitator having a collapsible bag with an outlet as recited in claim 3, wherein:

said self-sealing membrane is siliconized.

Claim 8. A medical port for an emergency safety resuscitator having a collapsible bag with an outlet, which comprises:

a tube constructed of rigid clear plastic having a first aperture for communicating with a collapsible bag of a resuscitator, a second aperture, a third aperture available for connection to a mask or an endotracheal tube, and an inside; and
a siliconized self-sealing membrane releasably covering the second aperture of said tube.

Claim 9. A medical port for an emergency safety resuscitator having a collapsible bag with an outlet, which comprises:

a tube having a first aperture for communicating with a collapsible bag of a resuscitator, a second aperture, a third aperture available for connection to a mask or an endotracheal tube, and an inside; and

a siliconized self-sealing membrane releasably covering the second aperture of said tube.

Claim 10. A medical port for an emergency safety resuscitator having a collapsible bag with an outlet, which comprises:

a tube having a first aperture for communicating with a collapsible bag of a resuscitator, a second aperture, a third aperture available for connection to a mask or an endotracheal tube, and an inside; and

two or more strips of flexible plastic, each strip having a first end attached to the inside of said tube, between the first aperture and the second aperture, and a second end pushing against a second end of at least one other of said strips.

Claim 11. The medical port for an emergency safety resuscitator having a collapsible bag with an outlet as recited in claim 10, wherein:

said tube is constructed of rigid clear plastic.

DATED this 29th day of October, 2004.

Thompson E. Fehr

Thompson E. Fehr
Attorney for Appellant

Registration No. 31,353

Suite 300
Goldenwest Corporate Center
5025 Adams Avenue
Ogden, Utah 84403

Telephone No.: (801) 393-6292



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TRANSMITTAL OF APPEAL BRIEF (PATENT APPLICATION-37 CFR 41.37)

1. Transmitted herewith is the APPEAL BRIEF in this application with respect to the Notice of Appeal filed on April 29, 2004.

2. STATUS OF APPLICANT

This application is on behalf of a small entity.

The statement of small entity status has already been filed.

3. FEE FOR FILING APPEAL BRIEF

Pursuant to 37 CFR 41.20(b)(2) the fee for filing the Appeal Brief is \$170.00.

Appeal Brief fee due \$170.00.

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4. EXTENSION OF TERM

The proceedings herein are for a patent application, and the provisions of 37 CFR 1.136 apply.

Applicant petitions for an extension of time under 37 CFR 1.136 (fees: 37 CFR 1.17(a)(1)-(5)) for a total of four months. The requisite fee for a small entity is \$765.00.

Fee \$765.00

5. TOTAL FEE DUE

The total fee due is

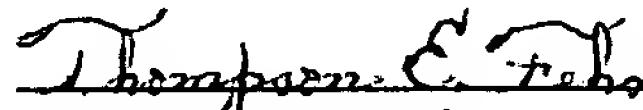
Appeal brief fee \$170.00

Extension fee \$765.00

TOTAL FEE DUE \$935.00

6. Attached is a check in the sum of \$935.00.

DATED this 29th day of October, 2004.



Thompson E. Fehr
Attorney for Appellant
Registration No. 31,353

Suite 300
Goldenwest Corporate Center
5025 Adams Avenue
Ogden, Utah 84403

Telephone: (801) 393-6292



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